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EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/814,143	Applicant(s) SUN ET AL.	
	Examiner Jennifer I. Harle	Art Unit 3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *20-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-58 were pending and subject a restriction requirement, Applicants elected Group I, claims 1-19 and withdrew claims 20-54. Thus, claims 1-19 remain pending. Independent claims 1 and 11 were amended by Applicants' Amendment, filed January 29, 2004, to recite the further limitation of a hand-held patient appliance. The new rejections of claims 1-19 is necessitated by Applicants' Amendment and is **made final**.

Response to Arguments

A. Restriction Requirement

Applicants affirmed the election of Group I, claims 1-19, without traverse and withdrew claims 20-58.

B. Information Disclosure Statement

The examiner thanks Applicants for the provision of the copy of the IDS.

C. Interpretation of the Claims Under 35 U.S.C. 116 6th Paragraph

As set forth by Applicant, claims 1, 3-4, and 10 are interpreted according the mean-plus function limitations.

D. Lexicography

The examiner notes Applicants' right to reserve the ability to be their own lexicographer. The examiner further notes the specific definition applied to the term presentation as set forth on page 26 of the current Amendment, filed January 29, 2004, i.e. "presentation" means both the content and the format that the information is provided to the user.

E. Amendments to the Specification

Applicants' request to change the title so that it more closely describes the invention in the pending, non-withdrawn claims. The examiner approves the change to the title.

F. Rejection of the Claims based on the Cited References

Due to Applicants' Amendment the rejections are withdrawn. The new rejections of claims 1-19 were necessitated by Applicants' Amendment and are **made final**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 8-15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Reed, et al. (US 2003/0114736 A1).

Reed discloses a medical information management system ([0016]-[0020], [0028]-[0032] – an integrated subject monitoring system that provides for the acquisition of health-related information to be collected, analyzed, manipulated, stored and output) comprising:

A hand-held patient appliance having an input/output device, a processor, and a memory, wherein a patient interacts with the patient appliance, via the input/output device according to a patient tailored presentation that is generated by the processor based on data stored in the memory, to provide medical information to the patient appliance, review information stored in the patient appliance, or both ([0034]-[0041], [0061]-[0067], [0081]-[0087] – discloses that each subject carries a small radio frequency (RF), infrared (IR), or other wireless personal transmitter that transmits the unique code of the subject, possesses a panic button that when activated issues an emergency call requesting immediate assistance and permits a customized response, receives information regarding movement, permits the subject to disable one or more parameters and utilizes a tone , vibration or synthesized voice or email message as a signal – thus it contains a processor, and memory, the patient interacts with the appliance, via the input/output device according to a patient tailored presentation that is generated by the processor and [0031]-0032], [0042]-[0043], [0088]-[0089] - subject inputs comments and non-observable complaints and symptoms and well as interactively enters subjective inputs, which would implicitly be tailored to be presented to the subject, as are the reviews and can be via a palmtop digital assistant as that is one of the disclosed remote nodes, includes the use of an oximeter for positive pressure therapy as set forth in the specification on page 23 at paragraph 57);

Means for selectively establishing a first communication link between the information management center and a patient appliance assigned to a patient whose medical information is being managed by the information management center for communicating data from the patient appliance to the information management center or from the information management center to the patient appliance (includes RF, IR or other wireless methods as set forth in the sections

disclosed above – the subject can utilize any of the remote nodes for subjective input and the personal medical device);

Means for selectively establishing a second communication link between the information management center and a healthcare professional terminal of a healthcare professional supervising a patient whose medical information is being managed by the information management center, wherein interaction between the healthcare professional terminal and the information management center via the second communication link is governed by a healthcare professional-management center protocol so that a healthcare professional interacting with the information management center via the healthcare professional terminal is provided with a healthcare professional tailored presentation different from the patient tailored presentation (Fig. 1; [0031]-[0033], [0088]-[0089], [0092]-[0097], [0109]-[0111], [0115]-[0116], [0118]-[0121] – discloses that the caregivers, doctors and researchers all receive customized, user-friendly formatted reports depending upon access controls through network connections and alerts or warning if the patient appliance provides information that falls outside a predetermined threshold, including the internet and that the information is also dependent upon the required needs of the healthcare professional at a given time and that the terminals can have voice recognition software to enter information without typing; caregivers can choose the rmotes nodes which can vary);

Means for selectively establishing a third communication link between the information management center and a third party terminal of a third party authorized by a patient whose information is being managed by the information management center to allow such a third party access to at least a portion of the medical information associated with such a patient for

reviewing same, wherein interaction between such a third party terminal and the information management center via the third communication link is governed by a third party management center protocol, so that a third party interacting with the information management center via the third party terminal to review the medical information associated with a patient is provided with a third party tailored presentation different from the patient tailored presentation and different from the healthcare professional tailored presentation (Fig. 1; [0031]-[0033], [0088]-[0089], [0092]-[0097], [0109], [0114] – discloses that the outputs are tailored for each receiving party and that family members receive customized, user-friendly formatted reports depending upon access controls, which can be limited by the amount of information the subject wants to provide, through network connections, including the internet and telephone).

Claims 11-15 and 17 are rejected for the same reasons as set forth above.

Claims 6-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed, et al. (US 2003/0114736 A1) in view of Coli, et al. (6, 018,713).

As per claims 7 and 16, Reed teaches as set forth above. However, Reed does not disclose a first field that is a patient field and a second field that is an advertisement field. Coli teaches that advertisements are utilized in a second field with health professionals, i.e. advertising for particular drug treatments or medical devices needed by patients may be provided as part of the test results reporting output (targeted advertising with hyperlinks) that includes full advisory information about the drug so that the physician can readily obtain information about possible treatments for conditions suggested by the test results. (col. 4, lines 19-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of including advertising as taught by Coli in Reed because the skilled artisan would have

recognized that this business practice permits the provider of the service generate a revenue stream by charging the advertisers and thus to recoup some of the costs of providing the service and thus keep the costs to the consumers and users down and increase his own profits.

As per claim 6, Reed teaches as set forth above. However, Reed does not disclose that the database is adapted to store general medical information not specific to the medical information associated with a patient. Coli discloses that tests that are can be ordered for patients are stored by category and descriptions and images of the tests are also stored so that a user can retrieve a clinical description of the test or demographic information, thus providing meaningful clinical groupings for consistent selection of tests to be performed, facilitates analysis and rapid recognition of clinical patterns and trends to facilitate accurate diagnosis and reporting of results (cols. 2-7). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the general information of Coli in Reed for the specific reasons set forth in Coli.

Assuming arguendo that Reed does not teach voice synthesizing as set forth in claims 8 and 17, claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed, et al. (US 2003/0114736 A1) in view of Abdoh (6, 564,207).

Reed teaches as set forth above. Assuming arguendo that Reed does not teach voice synthesizing, Abdoh teaches that voice synthesizing can be used to feed medical information for monitoring patients into a database by patients/health providers via a communications link. Abdoh further teaches that this method provides a versatile and flexible method of generating and storing multiple questionnaires and of collecting and analyzing responses to the questionnaires, eliminates the need for printing paper questionnaires, out-mailing and reply

postage costs, data entry errors and costs, statistical analysis costs, time lapse problems between mailing and getting the results analyzed, and it is flexible enough to be easily customized to meet each and every need in patient satisfaction, functional health status assessment, patient centered outcomes evaluation, etc. (cols. 3-4). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of voice synthesizing as set forth in Abdoh in Reed for the explicit reasons set forth in Abdoh.

Assuming arguendo that Reed does not disclose a hand-held patient appliance, claims 1-5, 8-15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed, et al. (US 2003/0114736 A1) in view of Joao (US 6,283,761) or Causey, II, et al. (6,641,533 B2), or Raymond, et al. (5778,882).

Reed discloses as set for above. Assuming arguend that Reed does not disclose a hand-held patient appliance, Joao, Causey, III and Raymond, all disclose the use of a hand-held patient appliance, i.e a pda, which requires that the patient interacts with the pda according to a survey, to provide some form of medical information to the patient appliance/review information stored in the patient appliance or both (Joao –cols. 14-20, 22-24, 26; Causey – Abstract, cols. 2-6, 8-27 – discloses that the pda can be interfaced with other monitors and medical devices, that it is interconnected to a communication station with a trained health care professional, utilized auditory feedback for the visually impaired, can be used by parents while children are sleeping, or doing other activities, can sound alarms – due to its size can be quiet and act in a discrete mode and be kept in the pocket, act like a pager, and has querying capabilities, travels with the individual and thus is able to receive updates and information to keep current; Raymond – Abstract, figs. 15-20, cols. 1-3, 5, 8, 24-27 – the advantages of a pda include the ability to record

events at any point during the day because it can be kept with the individual and because it is time stamped and interactive). Thus, it would have been obvious to one of ordinary skill in the art to have utilized a hand-held device as in Joao/Causey/Raymond in Reed for the explicit reasons set forth in Causey/Raymond.

Claims 6-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed, et al. (US 2003/0114736 A1) and Joao (US 6,283,761) or Causey, III, et al. (6,641,533 B2), or Raymond, et al. (5778,882) in view of Coli, et al. (6, 018,713).

As per claims 7 and 16, Reed and Joao/Causey/Raymond discloses as set forth above. However, Reed does not disclose a first field that is a patient field and a second field that is an advertisement field. Coli teaches that advertisements are utilized in a second field with health professionals, i.e. advertising for particular drug treatments or medical devices needed by patients may be provided as part of the test results reporting output (targeted advertising with hyperlinks) that includes full advisory information about the drug so that the physician can readily obtain information about possible treatments for conditions suggested by the test results. (col. 4, lines 19-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of including advertising as taught by Coli in Reed because the skilled artisan would have recognized that this business practice permits the provider of the service generate a revenue stream by charging the advertisers and thus to recoup some of the costs of providing the service and thus keep the costs to the consumers and users down and increase his own profits.

As per claim 6, Reed and Joao (US 6,283,761) or Causey, III, et al. (6,641,533 B2), or Raymond, et al. (5778,882) discloses as set forth above. However, Reed does not disclose that

the database is adapted to store general medical information not specific to the medical information associated with a patient. Coli discloses that tests that are can be ordered for patients are stored by category and descriptions and images of the tests are also stored so that a user can retrieve a clinical description of the test or demographic information, thus providing meaningful clinical groupings for consistent selection of tests to be performed, facilitates analysis and rapid recognition of clinical patterns and trends to facilitate accurate diagnosis and reporting of results (cols. 2-7). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the general information of Coli in Reed for the specific reasons set forth in Coli.

Assuming arguendo that Reed does not teach voice synthesizing as set forth in claims 8 and 17, claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed, et al. (US 2003/0114736 A1) and Joao (US 6,283,761) or Causey, III, et al. (6,641,533 B2), or Raymond, et al. (5778,882) in view of Abdoh (6, 564,207).

Reed and Joao/Causey/Raymond discloses as set forth above. Assuming arguendo that Reed does not teach voice synthesizing, Abdoh teaches that voice synthesizing can be used to feed medical information for monitoring patients into a database by patients/health providers via a communications link. Abdoh further teaches that this method provides a versatile and flexible method of generating and storing multiple questionnaires and of collecting and analyzing responses to the questionnaires, eliminates the need for printing paper questionnaires, out-mailing and reply postage costs, data entry errors and costs, statistical analysis costs, time lapse problems between mailing and getting the results analyzed, and it is flexible enough to be easily customized to meet each and every need in patient satisfaction, functional health status

assessment, patient centered outcomes evaluation, etc. (cols. 3-4). It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of voice synthesizing as set forth in Abdoh in Reed for the explicit reasons set forth in Abdoh.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In accordance with the USPTO's goals of customer service, compact prosecution, and reduction of cycle time, and because "the continual, chief complaint of inventors and their lawyers: that patent examiners are abysmal communicators, both orally and in writing,"[1] the Examiner has made every effort to clarify his position regarding claim interpretation and any rejections or objections in this application. Furthermore, the Examiner has provided Applicant(s) with notice—for due process purposes—of his position regarding his factual

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[1] Sabra Chartrand, *A Bid to Overcome Patent Backlogs*, 152 N.Y. Times C2 (Sept. 23, 2002).

determinations and legal conclusions. If Applicant(s) disagree with *any* factual determination or legal conclusion made by the Examiner in this Office Action whether expressly stated or implied,[2] the Examiner respectfully requests Applicant(s) *in their next response* to expressly traverse the Examiner's position and provide appropriate arguments in support thereof. Failure by Applicant(s) *in their next response* to traverse the Examiner's positions and provide appropriate arguments in support thereof will be considered an admission by Applicant(s) of the factual determinations and legal conclusion not expressly traversed.[3] By addressing these issues now, matters where the Examiner and Applicant(s) agree can be eliminated allowing the Examiner and Applicant(s) to focus on areas of disagreement (if any) with the goal towards allowance in the shortest possible time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is 703.306.2906. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703.308.5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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[2] E.g., if the Examiner rejected a claim under §103 with two references, although not directly stated, it is the Examiner's implied position that the references are analogous art.

[3] See also MPEP §714.02, 37 CFR §1.111(b), and 37 CFR §1.104(c)(3).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
March 27, 2004

Richard Chilcot
Supervisory Patent Examiner
Technology Center 2[illegible]